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To allow patients to receive any medical treatment they want under certain conditions and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 12, 1995

Mr. DEFAZIO (for himself, Mr. BARTON of Texas, Mr. DELAY, Mr. COX of California, Mr. HINCHEY, Mr. PALLONE, Mr. KINGSTON, Ms. FURSE, Ms. NORTON, Mr. OWENS, Mr. SMITH of New Jersey, Mr. LIPINSKI, Ms. VELÁZQUEZ, Mr. EVANS, Mr. DELLUMS, Mr. DEUTSCH, Mr. FRAZER, and Mr. HILLIARD) introduced the following bill; which was referred to the Committee on Commerce

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A BILL

To allow patients to receive any medical treatment they want under certain conditions and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Access to Medical Treatment Act''.

SEC. 2. DEFINITIONS.

As used in this Act:

(1) ADVERTISING CLAIMS.—The term ''advertising claims'' means any representations made or suggested by statement, word, design, device, sound, or any combination thereof with respect to a medical treatment.

(2) DANGER.—The term ''danger'' means any negative reaction that—

(A) causes serious harm;

(B) occurred as a result of a method of medical treatment;

(C) would not otherwise have occurred; and

(D) is more serious than reactions experienced with routinely used medical treatments for the same medical condition or conditions.

(3) DEVICE.—The term ''device'' has the same meaning given such term in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)).

(4) DRUG.—The term ''drug'' has the same meaning given such term in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)).

(5) FOOD.—The term ''food''—

(A) has the same meaning given such term in section 201(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(f)); and

(B) includes a dietary supplement as defined in section 201(ff) of such Act.

(6) HEALTH CARE PRACTITIONER.—The term ''health care practitioner'' means a physician or another person who is legally authorized to provide health professional services in the State in which the services are provided.

(7) LABEL.—The term ''label'' has the same meaning given such term in section 201(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(k)) and includes labeling as defined in section 201(m) of such Act (21 U.S.C. 321(m)).

(8) LEGAL REPRESENTATIVE.—The term ''legal representative'' means a parent or an individual who qualifies as a legal guardian under State law.

(9) SELLER.—The term ''seller'' means a person, company, or organization that receives payment related to a medical treatment of a patient of a health practitioner, except that this term does not apply to a health care practitioner who receives payment from an individual or representative of such in-

dividual for the administration of a medical treatment to such individual.

(10) MEDICAL TREATMENT.—The term ''medical treatment'' means any food, drug, device, or procedure that is used and intended as a cure, mitigation, treatment, or prevention of disease.

SEC. 3. ACCESS TO MEDICAL TREATMENT.

(a) IN GENERAL.—Notwithstanding any other provision of law, and except as provided in subsection (b), an individual shall have the right to be treated by a health care practitioner with any medical treatment (including a medical treatment that is not approved, certified, or licensed by the Secretary of Health and Human Services) that such individual desires or the legal representative of such individual authorizes if—

(1) such practitioner has personally examined such individual and agrees to treat such individual; and

(2) the administration of such treatment does not violate licensing laws.

(b) MEDICAL TREATMENT REQUIREMENTS.—A health care practitioner may provide any medical treatment to an individual described in subsection (a) if—

(1) there is no reasonable basis to conclude that the medical treatment itself, when used as directed,

poses an unreasonable and significant risk of danger to such individual;

(2) in the case of an individual whose treatment is the administration of a food, drug, or device that has to be approved, certified, or licensed by the Secretary of Health and Human Services, but has not been approved, certified, or licensed by the Secretary of Health and Human Services—

(A) such individual has been informed in writing that such food, drug, or device has not yet been approved, certified, or licensed by the Secretary of Health and Human Services for use as a medical treatment for the condition of such individual; and

(B) prior to the administration of such treatment, the practitioner has provided the patient a written statement that states the following:

''WARNING: This food, drug, or device has not been declared to be safe and effective by the Federal Government and any individual who uses such food, drug, or device, does so at his or her own risk.'';

(3) such individual has been informed in writing of the nature of the medical treatment, including—

(A) the contents and methods of such treatment;

(B) the anticipated benefits of such treatment;

(C) any reasonably foreseeable side effects that may result from such treatment;

(D) the results of past applications of such treatment by the health care practitioner and others; and

(E) any other information necessary to fully meet the requirements for informed consent of human subjects prescribed by regulations issued by the Food and Drug Administration;

(4) except as provided in subsection (c), there have been no advertising claims made with respect to the efficacy of the medical treatment by the practitioner, manufacturer, or distributor;

(5) the label of any drug, device, or food used in such treatment is not false or misleading; and

(6) such individual—

(A) has been provided a written statement that such individual has been fully informed with respect to the information described in paragraphs (1) through (4);

(B) desires such treatment; and

(C) signs such statement.

In any proceeding relating to the enforcement of paragraph (5) with respect to the label of drugs, devices, or food used in medical treatment covered under this subsection, the provisions of section 403B(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343-2(c)) shall apply to establishing the burden of proof that such label is false or misleading.

(c) CLAIM EXCEPTIONS.—

(1) REPORTING BY A PRACTITIONER.—Subsection (b)(4) shall not apply to an accurate and truthful reporting by a health care practitioner of the results of the practitioner's administration of a medical treatment in recognized journals or at seminars, conventions, or similar meetings or to others so long as the reporting practitioner has no financial interests in the reporting of the material and has received no financial benefit of any kind from the manufacturer, distributor, or other seller for such reporting. Such reporting may not be used by a

manufacturer, distributor, or other seller to advance the sale of such treatment.

(2) STATEMENTS BY A PRACTITIONER TO A PATIENT.—Subsection (b)(4) shall not apply to any statement made in person by a health care practitioner to an individual patient or an individual prospective patient.

(3) DIETARY SUPPLEMENTS STATEMENTS.—Subsection (b)(4) shall not apply to statements or claims permitted under sections 403B and 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343-2 and 343(r)(6)).

SEC. 4. REPORTING OF A DANGEROUS MEDICAL TREATMENT.

(a) HEALTH CARE PRACTITIONER.—If a health care practitioner, after administering a medical treatment, discovers that the treatment itself was a danger to the individual receiving such treatment, the practitioner shall immediately report to the Secretary of Health and Human Services the nature of such treatment, the results of such treatment, the complete protocol of such treatment, and the source from which such treatment or any part thereof was obtained.

(b) SECRETARY.—Upon confirmation that a medical treatment has proven dangerous to an individual, the Sec-

retary of Health and Human Services shall properly disseminate information with respect to the danger of the medical treatment.

SEC. 5 REPORTING OF A BENEFICIAL MEDICAL TREATMENT.

If a health care practitioner, after administering a medical treatment that is not a conventional medical treatment for a life-threatening medical condition or conditions, discovers that, in the opinion of the practitioner, such medical treatment has positive effects on such condition or conditions that are significantly greater than the positive effects that are expected from a conventional medical treatment for the same condition or conditions, the practitioner shall immediately make a reporting, which is accurate and truthful, to the Office of Alternative Medicine of—

(1) the nature of such medical treatment (which is not a conventional medical treatment);

(2) the results of such treatment; and

(3) the protocol of such treatment.

SEC. 6. TRANSPORTATION AND PRODUCTION OF FOOD, DRUGS, DEVICES, AND OTHER EQUIPMENT.

Notwithstanding any other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 201 et seq.), a person may—

(1) introduce or deliver into interstate commerce a food, drug, device, or any other equipment; and

(2) produce a food, drug, device, or any other equipment,

solely for use in accordance with this Act if there have been no advertising claims by the manufacturer, distributor, or seller.

SEC. 7. VIOLATION OF THE CONTROLLED SUBSTANCES ACT.

A health care practitioner, manufacturer, distributor, or other seller may not violate any provision of the Controlled Substances Act (21 U.S.C. 801 et seq.) in the provision of medical treatment in accordance with this Act.

SEC. 8. PENALTY.

A health care practitioner who knowingly violates any provision of this Act shall not be covered by the protections under this Act and shall be subject to all other applicable laws and regulations.

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